

PSJ14 Janssen Opp Exh 19 – JAN-MS-00309606

DURAGESIC

Positioning Evolution Overview

June 1, 2002

DURAGESIC Positioning Statement Research

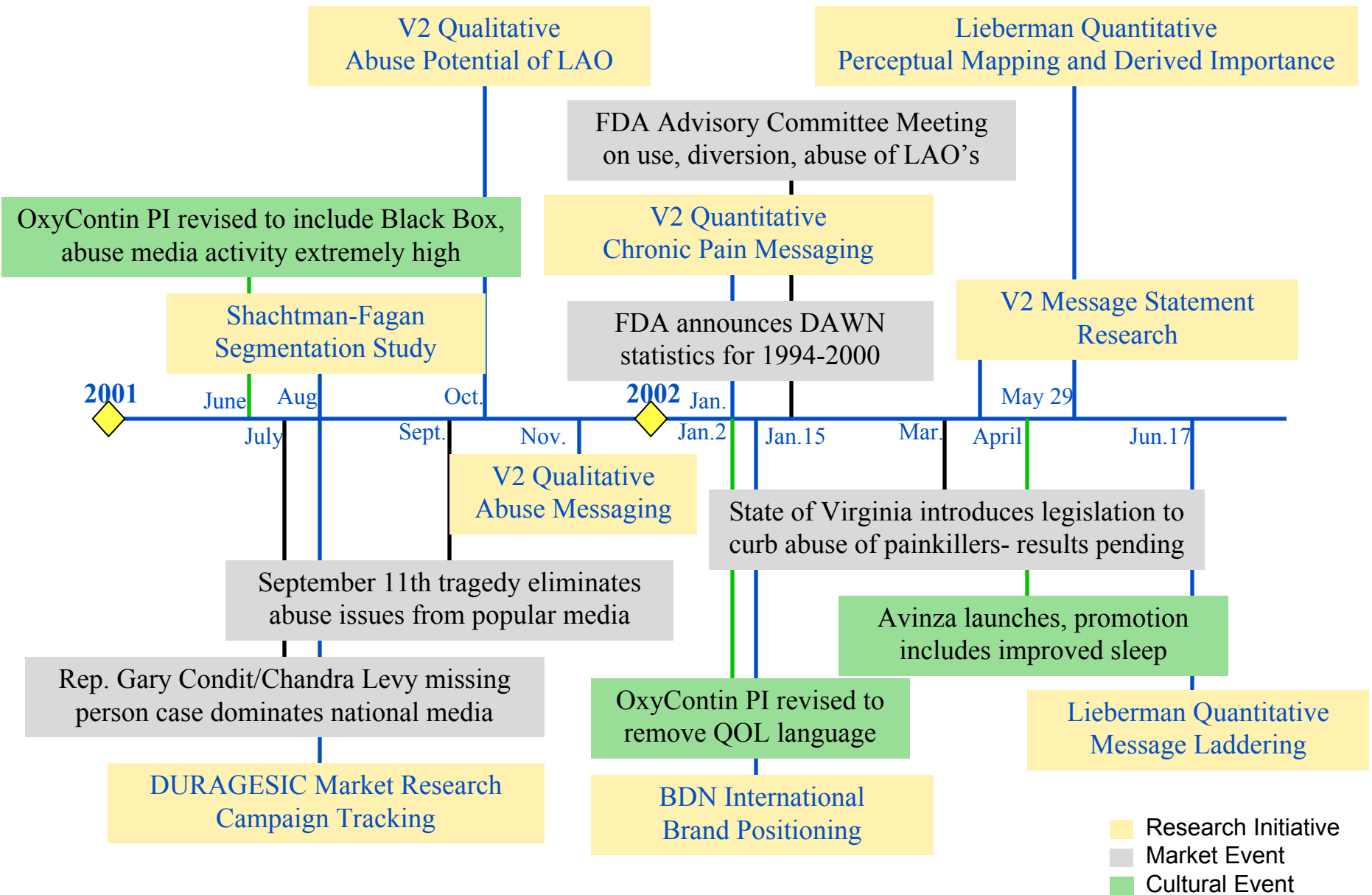
- Research Initiatives Timeline
 - August 2001, Shachtman-Fagan Segmentation Study (n=540)
 - August 2001, DURAGESIC Market Research Campaign Tracking, Source PERQ/HCI September 2001(n=225)
 - October 2001, V2 A Qualitative Assessment of Abuse Potential of Long-Acting Opioids Used in the Treatment of Chronic Pain (n=16 focus groups)
 - November 2001, V2 DURAGESIC Message Testing: Incorporating an Abuse-Related Message (n=39)
 - December/January V2 Chronic Pain Message Evaluation (n=242)
 - January 15, 2002, BDN Brand Positioning Workshop
 - March/April 2002, V2 Message Statement Research (n=58)
 - May 29, 2002, Lieberman Perceptual Mapping and Derived Importance (n=540)
 - June 17, 2002, Lieberman Message Laddering (n=540)

DURAGESIC Positioning Statement Events

- Market & Cultural Events

- OxyContin PI change: June '01 - Addition of Black Box Warning
- Gary Condit: July '01 - Questioned regarding the April 30th disappearance of intern Chandra Levy, popular media coverage of OxyContin abuse diminishes
- September 11th Tragedy - National and international media attention focused entirely upon terrorist attacks and activity, abuse stories forgotten
- DAWN Data: January '02 - FDA announces DAWN Data for 1994-2000, popular media coverage of abuse of LAO's resumes
- Oxycontin PI change: January '02 - Removal of any references to QOL/mood/sleep (opportunity)
- State of Virginia: March '02 - Legislation introduced with intention to reduce abuse of painkillers through tighter restrictions governing prescriptions, results pending
- Avinza launch: April '02 - Has references to improvements in sleep in OA study (potential threat/noise, esp. with Elan salesforce of 450 PCP reps and 140 Neuro reps)

DURAGESIC Positioning Statement Research & Events Timeline



DURAGESIC Positioning Statement

Conclusions

- Implications of Results
 - Providing patients with consistent relief that helps to improve functionality represents the primary goal of therapy
 - DURAGESIC features and benefits can be crafted to insure ownership of and success with improved functionality message
 - Results underscore that sales training, in addition to revision of promotional materials, must create the appropriate links between consistency, efficacy, and functionality

- New DURAGESIC Positioning Statement
 - *DURAGESIC® significantly improves physical and social functioning by providing the only chronic pain relief that is consistent and effective for up to 72 hours.*

DURAGESIC

Journal Advertising Overview

March 1991-Present

DURAGESIC Ad Campaign Overview

March 1991

- Focus on introduction of patch technology providing 72 hours of relief to malignant chronic pain patients

May 1994

- Promotion of around-the-clock control highlights benefits of 72 hour efficacy in limiting breakthrough pain associated with oral medications
- Shift away from limiting consideration to only malignant patients

April 1995

- Strongly promoting relief from breakthrough pain through illustration of consistent serum level profile

July 1997

- Illustrates an effort to “humanize” chronic pain by focusing on patient benefits of 72 hour dosing & serum levels versus oral medications

October 1998

- Continuing with patient benefits, promotion of treatment simplicity due to 72 hour dosing regimen

October 2000

- First movement towards returning to a more normal life as a patient benefit since 72 hour dosing and less breakthrough pain allow for fewer interruptions
- Current concept exploration grows upon this concept to highlight restoration of functionality as a treatment goal of both patients and physicians

March 1991

For patients who need oral morphine
or other opioids for chronic cancer pain...

**AVAILABLE SOON FROM
JANSSEN PHARMACEUTICA
NEW DURAGESIC**



Duragesic®
FENTANYL
TRANSDERMAL SYSTEM

**PAIN CONTROL
THAT
GOES ON...**

- The first and only opioid in a transdermal patch
- Can provide 72 hours of pain control with each application
- Proven effective for the long-term management of cancer pain
- Available in four color-coded dosage strengths providing continuous delivery of 25 µg/hr, 50 µg/hr, 75 µg/hr, or 100 µg/hr of fentanyl for 72 hours

To see a Janssen representative,
Please call 1-800-833-8033 or call to 5 PM
Eastern time, Monday through Friday.
See following page for brief summary of Prescribing Information.
For use only in opioid tolerant patients.

© Janssen Pharmaceutica Inc. 1991

Coming Soon Journal Ad

Headline: Available Soon From
Janssen Pharmaceutica
New DURAGESIC

Tagline: Pain Control That
Goes On...

Format: One Page Journal Ad

April 1991-December 1992



**Now Available
Launch Journal
Ads**

Headline: 72 Hours Of
Pain Control From A
Single Dose...

Tagline: Pain Control
That Goes On...

Format: 3 Page Journal
Ad



Headline: 72 Hours Of Pain
Control In A Transdermal Patch

Tagline: Pain Control That Goes
On...

Format: One Page Journal Ad

May 1994-March 1995



Core Campaign Journal Ad

Headline: Around-the-clock chronic pain control when your patient needs it.

Tagline: Chronic Pain Control That Goes On...

Format: One Page Journal Ad

Why interrupt these moments with oral opioid dosing?





Choose DURAGESIC[®]
3 days of reliable analgesic



3-day dosing interval enables patients to shed their mental logs

- allows continuous relief of unrelenting pain
- eliminates "watching the clock" between doses (reduces time and effort for the patient and family)

Minimizes the peaks and troughs of oral opioids

- in cancer patients
 - low incidence of hypoxemia (<1%)
 - low incidence of hypotension (<2%)

Available in 25 mg/hrs, 75 mg/hrs, and 100 mg/hrs patches

- Doses exceeding 25 mg/hrs should be used at the discretion of your physician

delivery in 1 convenient patch



For patients in chronic pain who require continuous opioid analgesia... analgesic effects can be managed by doses means such as administration of oral morphine, hydromorphone, or oxycodone, along with short-acting opioids.

Breaker in the risk of serious hypoxemia, hypotension, or respiratory depression in the management of acute or chronic pain, or not monitored, pain response to pain of hypoxemia/hypotension.

Tagline: Chronic Pain
Control That Goes
On...

**Format: 3 Page
Journal Ad**

July 1997-May 1998



For chronic pain

*"I saw how constipated and groggy
the pain pills made my friends.
I didn't want those same problems..."*

In an open cross-over clinical trial (n=200), patients who were given DURAGESIC[®] experienced pain control comparable to morphine, but suffered significantly less constipation (p<0.001). Patients also experienced significantly less daytime drowsiness (p<0.015) with DURAGESIC[®]. In a cross-sectional study (n=515), cancer patients reported significantly less frequency (p<0.004) and impact (p<0.001) of side effects with DURAGESIC[®] than with morphine.¹ This study also suggests that DURAGESIC[®] patients are more satisfied with their medication.² That's pain control your patients can live with.

For patients in chronic pain who require continuous opioid analgesia and whose chronic pain cannot be managed by lesser means such as nonsteroidal anti-inflammatory drugs, nonopioid analgesics, or pain-relieving with short-acting opioids.

Because of the risk of serious hyperventilation, DURAGESIC[®] is contraindicated in the management of acute or postoperative pain, or mild, intermittent pain responsive to p.r.n. or non-opioid therapy.

With some other sedatives or tranquilizers, the risk of severe hyperventilation may be increased. Alcohol, smoking, or other factors may also affect the action of DURAGESIC[®]. Always report these to your doctor. This and other risks may occur only if you misuse it or if you have a history of alcohol abuse.

Please see adjacent page for full text of prescribing information, including full warning.

Duragesic[®]
FENTANYL TRANSDERMAL
SYSTEM

Stops the pain. Not the patient.

Core Campaign Journal Ad

Headline: "I saw how constipated and groggy the pain pills made my friends. I didn't want those same problems."

Tagline: Stops the Pain. Not the Patient.

Format: Spread
Journal Ad



Tagline: Around-the-Clock Living.

Format: Spread Journal Ad

October 2000-Present

“This day will be a lifelong memory. I’m glad chronic pain won’t be a part of it.”

Patients prefer¹ the DURAGESIC[®] patch. DURAGESIC[®] only needs to be applied **once every 3 days**, maintains consistent serum levels over **72 hours**, and has a **favorable side-effect profile**. So give your patients a life not disrupted by chronic pain.

Life, uninterrupted.

Duragesic[®]
FENTANYL TRANSDERMAL SYSTEM

DURAGESIC[®] is indicated for patients in chronic pain who require continuous opioid analgesia and whose pain cannot be managed by lesser means such as nonsteroidal anti-inflammatory drugs, narcotic analgesics, or oral dosing with short-acting opioids.

The most common adverse experience included nausea (27%), vomiting (27%), constipation (27%), drowsiness (27%), dry mouth (27%), dizziness (27%), and headache (27%). Other patients were reporting other symptoms. Including the following were reduced.

Please see relevant pages for full prescribing information, including boxed warning.

Reference: 1. Journal of Clinical Pharmacy and Therapeutics, 2008; 33: 1-10. Duragesic[®] is a registered trademark of Janssen-Cilag Inc. © 2008 Janssen-Cilag Inc.

*See relevant pages for full prescribing information. Duragesic[®] is a registered trademark of Janssen-Cilag Inc. © 2008 Janssen-Cilag Inc.

www.duragesic.com

Core Campaign Journal Ad

Headline: “This day will be a lifelong memory. I’m glad chronic pain won’t be a part of it.”

Tagline: Life, uninterrupted.

Format: Spread Journal Ad



Tagline: Life,
uninterrupted.

Format: Spread Journal Ad



Tagline: Life,
uninterrupted.

Format: Spread
Journal Ad

Concept Development



**WORK. PLAY. STAND.
SIT. BEND. STRETCH.
MOVE.**

CARRY.

Chronic pain relief that improves physical and social functioning^{1,2}

- Provides uninterrupted pain relief for up to 72 hours with fewer peaks and troughs³
- Helps patients think less about their pain
- Improvements in functioning at month 12^{1,2}

Duragesic®
FENTANYL TRANSDERMAL SYSTEM

Life, uninterrupted.

DURAGESIC is indicated for patients in chronic pain who require continuous opioid analgesia and whose pain cannot be managed by non-opioid means such as nonsteroidal anti-inflammatory drugs, acetaminophen, or other drugs with opioid-sparing effects.

The most common adverse experiences included nausea (25%), constipation (22%), drowsiness (17%), somnolence (14%), dry mouth (13%), dizziness (12%), weakness (10%), euphoria (8%), dysphoria (7%), and somnolence (6%). Many patients were receiving other analgesics, including chronic opioid analgesics.

A Duragesic transdermal study enrolled 102 patients with chronic pain. The study was designed to evaluate the safety and efficacy of Duragesic compared to morphine. The study was conducted in a 12-month, double-blind, randomized, controlled trial. The study was designed to evaluate the safety and efficacy of Duragesic compared to morphine. The study was conducted in a 12-month, double-blind, randomized, controlled trial.

The Duragesic transdermal system compares to other chronic pain management systems by providing continuous pain relief for up to 72 hours. Unlike the oral opioid analgesics, Duragesic provides continuous pain relief for up to 72 hours. Unlike the oral opioid analgesics, Duragesic provides continuous pain relief for up to 72 hours.

Please see important information for use of Duragesic on the inside of the Duragesic box.

Refreshing Core Campaign Journal Ad

Headline: “Work. Play. Stand. Sit. Bend. Stretch. Move. Carry.”

Tagline: Life, uninterrupted.

Format: Spread Journal Ad

Current DURAGESIC Ad Campaign Research

Rationale

- To optimize revised positioning statement, concept exploration to evolve the “Life, uninterrupted” campaign was initiated

Results

- Qualitative and Eye-Tracking research indicate both the current journal ad and “Baker” concept communicate restoration of physical and social functioning
- Additional qualitative and quantitative research is planned to refine final execution